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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,245	06/07/2005	David Feifel	034123-122	3580

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EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/538,245	FEIFEL, DAVID	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10 and 15-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10 drawn to a method for the identifying an agent for treating neuropsychiatric disorders.

Group II, claim(s) 15-18, 21-23 and 31-34, drawn to a method for modulating sensory motor gating and improving cognitive function by administration of neurotensin to a subject.

Group III, claim(s) 15-18, 21-23 and 31-34, drawn to a method for modulating sensory motor gating and improving cognitive function by administration of neurotensin analog to a subject.

Group IV, claim(s) 15-34, drawn to a method for modulating sensory motor gating or inhibiting serotonin-2A and/'or alpha-1 receptor mediated neural function and improving cognitive function by administration of neurotensin agonist to a subject.

Group V, claim(s) 15-18, 21-23, drawn to a modulating sensory motor gating by administration of neurotensin mimetic to a subject.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of identifying an agent for the treatment of neuropsychiatric disorders comprising administering an agent to an animal having inherently reduced prepulse inhibition, subjecting the animal to a startle stimulus and

observing the prepulse inhibition levels, which is not required by the other methods of Groups II-V.

Group II recites the special technical feature of modulating sensory motor gating by administration of neurotensin to a subject, which is not required by the other methods of Groups I and III-V.

Group III recites the special technical feature of modulating sensory motor gating by administration of neurotensin analog to a subject, which is not required by the other methods of Groups I, II, IV and V.

Group IV recites the special technical feature of modulating sensory motor gating or inhibiting serotonin-2A mediated neural function by administration of neurotensin agonist to a subject, which is not required by the other methods of Groups I-III and V.

Group V recites the special technical feature of modulating sensory motor gating by administration of neurotensin mimetic to a subject, which is not required by the other methods of Group I-IV.

3. Species Election

A) Startle stimulus

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Auditory stimulus

b) Visual stimulus

c) Nocioceptive stimulus

The claims are deemed to correspond to the species listed above in the following manner:

Claim 5
The following claim(s) are generic: 1 and 7.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above startle stimulus are distinct having different sensory responses and evaluation protocols. For example, the special technical feature of (a) is auditory stimulus. This special technical feature is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

B) Neuropsychiatric disorder

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

d) Schizophrenia

e) Schizoaffective disorder

f) Bipolar Disorder

g) Huntingdon's Disorder

h) Tourette Disorder

i) Obsessive-Compulsive Disorder

j) Major depression/psychotic depression/postpartum

depression/depression/manic depression

k) Anxiety

l) Autism

m) Affective disorder

n) Schizophreniform Disorder

o) Delusional disorder

p) Psychotic disorder

q) Borderline personality disorder

r) Post-traumatic stress disorder

s) Pervasive developmental disorder

t) Tic disorders

u) Sensorimotor gating abnormalities

The claims are deemed to correspond to the species listed above in the following manner: Claims 6, 10, 22, 23 and 30

The following claim(s) are generic: 1, 7, 15, 16, 21, 24 and 29
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above neurodegenerative diseases will determine characteristically different etiology, treatment options and levels of success from one another and, therefore, will represent a patentably distinct invention and would require a separate search of the art that would

be burdensome to the examiner. For example, the special technical feature of (d) is schizophrenia. This special technical feature is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

C) Neurotensin or Neurotensin agonist

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as listed in claims 17, 19, 20, 25, 27 and 28.

The claims are deemed to correspond to the species listed above in the following manner: Claims 17, 19, 20, 25, 27 and 28.

The following claim(s) are generic: 15, 16, 24, 26, 31 and 32.
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above compounds have

different structure and functional characteristics. For example, the special technical feature of one species is neurotensin (from about residue x to about residue 13 of SEQ ID NO: 1, wherein x can be comprising of a fragment of (Boc-Lys9)-neurotenin(9-13)-methyl ester. This special technical feature is not shared by the other species.

Applicant must select one species of neurotensin or neurotensin agonist for consideration.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. In response to this Office Action/Election requirement, applicant must elect one from Groups I-V and must additionally elect a species of startle stimulus, neuropsyciatric disorder and neurotensin or neurotensin agonist for consideration.

6. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Advisory Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
25 September 2006

Bridget C. Bunner

BRIDGET BUNNER
PATENT EXAMINER